

Remarks

This Amendment is in response to the Office Action dated **January 7, 2009**.

Rejections

35 U.S.C. §112

Claims 11-16 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is asserted in the Final Office Action that “[c]laim 11 is dependent on a cancelled claim (claim 3) and it is unclear which claim Applicant intended claim 11 to depend from ... For the purpose of examination of the claims, claim 11 will be treated as being dependent from claim 1.”

Claim 11 has been amended to depend from claim 1.

35 U.S.C. §102(e)

Claim 17 has been rejected under 35 U. S.C. §102(e) as being anticipated by Zamore (U S Patent Application No 2004/0093008). It is asserted in the Final Office Action that:

Zamore discloses a dilatation balloon with a first and second waist portion, a first and second cone portion, and a body portion where the balloon is formed of a first polymeric composition that forms a first layer (A) and a second layer (B) on at least one of the cone portions of the balloon formed from a second composition which is crosslinked to form a compression region.

Final Office Action, pp. 2-3, no. 4

Claims 17 has been amended in accordance with claim 1 to further recite that the balloon has a body portion that is uncrosslinked. Claim 17 is now directed to an embodiment of a

dilatation balloon for use in combination with a catheter device, the balloon having waist portions, cone portions and a body portion, the balloon formed of a first polymeric composition forming a first layer and having a second layer formed on at least a portion of the first layer.

The second layer comprises a second polymeric composition which is crosslinked to form a compression region on at least a portion of the balloon, the second polymer composition is crosslinked on the waist portions, the cone portions, or both, and the body portion is uncrosslinked.

Zamore fails to disclose or suggest a balloon having a body portion that is uncrosslinked. At most, Zamore disclose in paragraph [0037], that one or both ends of the tubing may be non-crosslinked for purposes of welding, but the central portion of the Zamore balloon is crosslinked:

[0037]... One embodiment of a means for welding a crosslinked balloon to a catheter shaft would be to weld or otherwise attach lengths of compatible and uncrosslinkable polymer tubing to one or both ends of a length of crosslinkable polymer tubing prior to exposure of the tubing assembly to crosslinking energy. The result would be a length of tubing consisting of a central crosslinkable section with a non-crosslinkable section at one or both outer ends. Upon exposure to crosslinking energy, only the central portion will crosslink, while the outer end or ends will remain uncrosslinked ...

Zamore does not anticipate claim 17 as amended. Applicants respectfully request withdrawal of this rejection.

35 U.S.C. §103(a)

Claims 1, 6-9, 11 and 12

Claims 1, 6-9, 11 and 12 have been rejected under 35 U.S.C. §103(a) as being obvious over Zamore in view of Pederson, Jr. et al (U.S. Patent Application Publication No 2004/0073250).

Claim 1 of the present application is directed to an embodiment of a dilatation balloon having waist portions, cone portions and a body portion, the balloon formed of a first polymeric composition forming a first layer, the balloon having a second layer formed on at least a portion of the first layer, the second layer comprising a second polymeric composition which is crosslinked to form a compression region on the waist portions, the cone portions, or both, while the body portion is uncrosslinked. Other features are recited.

It is asserted in the Final Office Action that:

Zamore discloses the balloon substantially as claimed. However, Zamore is silent to the specifics of the body portion of the balloon being uncrosslinked. Pederson, Jr. et al disclose a dilatation balloon with waist portions (16), cone portions (14), and a body portion (12) where the balloon may be comprised of a combination of materials and may be multilayered (paragraph [0043]). and may be multilayered (paragraph [0043]) . In paragraph [0029], Pederson, Jr. et al. disclose that the body portion of the balloon engages a patients vessel wall or the inner diameter of a stent when the balloon is inflated. Pederson, Jr. et al also disclose that the balloon material may be crosslinked or uncrosslinked depending on the material used for the balloon and the desired characteristics for the specific application (paragraph [0044]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the body portion of the balloon of Zamore as an uncrosslinked portion as taught by Pederson, Jr. et al as both Zamore and Pederson, Jr. et al disclose a multilayered balloon where the balloon material can be crosslinked or uncrosslinked and Pederson, Jr. et al teach that it is well known to use a uncrosslinked material for the balloon if desired for a specific application and also indicate that the body portion of the balloon, which can comprise the majority of the length of the balloon, is the portion that engages the vessel wall or stent. Thus, the body portion could be chosen to be uncrosslinked

depending on the specific application of the balloon.

Final Office Action, pp. 3-4, no. 6

This is incorrect.

Zamore discloses crosslinking the entire tubular member, or crosslinking of the middle portion, and optionally leaving the ends uncrosslinked for welding the tubular member to a shaft, for example. See paragraph [0037].

Zamore fails to disclose or suggest a balloon wherein the middle portion is uncrosslinked as discussed above.

Pederson, Jr. et al. do disclose that the balloon may be multilayered (par [0043]) and that the balloon may be crosslinked or uncrosslinked (par [0044]). However, the disclosure of Pederson, Jr. et al., when combined with Zamore, would lead one of skill in the art to crosslink the body portion of the balloon, and optionally not the ends. Paragraph [0044] of Pederson, Jr. et al. is reproduced below:

[0044] The balloon material may further be crosslinked or uncrosslinked, depending upon the nature of the material and the characteristics desired for a particular application. Generally speaking, crosslinking a balloon material can result in greater control over the final inflated balloon size. That is, after crosslinking, initial pressurization, expansion, and preshrinking, a balloon so treated may thereafter expand in a more controlled manner to a reproducible diameter in response to a given inflation pressure, relative to an uncrosslinked balloon comprising similar material. If desired, crosslinking can be performed by any conventional crosslinking process, such as, for example, thermal treatment and/or E-beam exposure.

Due to the fact that Pederson, Jr. et al. disclose crosslinking with respect to controlling the final inflated balloon size, i.e. the diameter, one of skill in the art would be lead to crosslink the body portion. Therefore, the disclosure of Pederson, Jr. et al. combined with Zamore would lead one at most, to leave the ends of the balloon uncrosslinked for welding

purposes, but certainly not the body or central portion of the balloon. This would only be done using impermissible hindsight, using Applicants' own invention because crosslinking of the waist and/or cone portions, but not the body or central portion of the balloon is found only within Applicants' disclosure. "... [I]mpermissible hindsight must be avoided and the legal conclusion must be reached on the basis of the facts gleaned from the prior art." MPEP 2142.

No *prima facie* showing of obviousness has been established with respect to claim 1. The combination lacks the elements recited in claim 1. *Prima facie* obviousness under 35 U.S.C. §103(a) requires that the combination of references teach or suggest all of the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). See also MPEP 2143.

In fact, Zamore actually teach away from crosslinking the waist portions of a balloon when the balloon is secured to a catheter shaft by welding, which is a typical manner of securement, because they state that "... [i]n the instance where a balloon element is composed of a crosslinked polymer, the welding cannot be performed since a crosslinked polymer is a thermoset, no longer melts and usually will not bond to the shafts" Teaching away is a secondary consideration that can be used to rebut any *prima facie* showing of obviousness if one can be established. However, in this instance, no *prima facie* showing of obviousness can be established. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2D 1385, 1390 (U.S. 2007).

Claims 6-9, 11 and 12 depend from claim 1 and are not obvious over this combination for at least the reasons that claim 1 is not obvious over this combination. Withdrawal of the rejection of claims 6-9, 11 and 12 under 35 U.S.C. §103(a) as being obvious over Zamore in view of Pederson, Jr. et al (U.S. Patent Application Publication No

2004/0073250) is respectfully requested.

Claims 1, 5-9 and 11-13

Claims 1, 5-9 and 11-13 have been rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al (U.S. Patent No. 5,344,400) in view of Zamore (U.S. Patent Application No.. 2004/0093008) and in view of Pederson, Jr. et al. It is asserted in the Final Office Action that:

Kaneko et al and Zamore disclose the balloon substantially as claimed. However, Kaneko et al and Zamore are silent to the specifics of the body portion of the balloon being uncrosslinked. Pederson, Jr et al disclose a dilatation balloon with waist portions (16), cone portions (14), and a body portion (12) where the balloon may be comprised of a combination of materials and may be multilayered (paragraph [0043]). In paragraph [0029], Pederson, Jr. et al. disclose that the body portion of the balloon engages a patients vessel wall or the inner diameter of a stent when the balloon is inflated. Pederson, Jr et al also disclose that the balloon material may be crosslinked or uncrosslinked depending on the material used for the balloon and the desired characteristics for the specific application (paragraph [0044]). It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the body portion of the balloon of Kaneko et al and Zamore as an uncrosslinked portion as taught by Pederson, Jr.. et al as Kaneko et al, Zamore, and Pederson, Jr. et al all disclose a multilayered balloon where the balloon material can be crosslinked or uncrosslinked and Pederson, Jr. et al teach that it is well known to use a uncrosslinked material for the balloon if desired for a specific application and also indicate that the body portion of the balloon, which can comprise the majority of the length of the balloon, is the portion that engages the vessel wall or stent Thus, the body portion could be chosen to be uncrosslinked depending on the specific application of the balloon.

Final Office Action, p. 6 (last sentence) to p. 7

Applicants disagree.

As admitted in the Final Office Action, Kaneko et al. is silent as to employing crosslinking of any polymer layer whatsoever.

Zamore discloses crosslinking the entire tubular member, or crosslinking of the middle portion, and optionally leaving the ends uncrosslinked for welding the tubular member to a

shaft, for example. See paragraph [0037].

As admitted in the Final Office Action, both Kaneko et al. and Zamore are silent as to the body portion of the balloon being uncrosslinked (see paragraph, pp. 6-7, reproduced above).

While true that Pederson, Jr. et al. disclose both multilayers and crosslinking, based on the disclosure of Pederson, Jr. et al. that crosslinking be used to control balloon expansion, one would be lead to crosslink the central or body portion of the Pederson, Jr. et al. balloon to control diameter size for expanding in a patient's vessel.

Therefore, the combination at most would lead one of skill in the art to crosslink the whole tubular member, or the body while optionally leaving the ends uncrosslinked for welding, but not to crosslink waist and/or cone portions with an uncrosslinked body portion, as recited in claim 1.

Claim 1 is not obvious over this combination. No *prima facie* showing of obviousness has been established. See *In re Vaeck*, 20 USPQ2d at 1442 (Fed. Cir. 1991). See also MPEP 2143.

Claims 5-9 and 11-13 depend from claim 1 and are not obvious over this combination for at least the reasons that claim 1 is not obvious over this combination.

Withdrawal of the rejection of claims 1, 5-9 and 11-13 under 35 U.S.C. §103(a) as being obvious over Kaneko et al (U.S. Patent No. 5,344,400) in view of Zamore (U.S. Patent Application No.. 2004/0093008) and in view of Pederson, Jr. et al., is respectfully requested.

Claims 5 and 13

Claims 5 and 13 have been rejected under 35 U.S.C. §103(a) as being obvious over Zamore in view of Pederson, Jr. et al as applied to claims 1 and 11 above, and further in view of Kaneko et al.

As discussed above, the combination of Zamore and Pederson, Jr. et al., fail to render claim 1 obvious. In the Final Office Action, Kaneko et al. is combined in this rejection for a tie layer. See Final Office Action, pp. 4-5, no. 8, Combining the tie layer of Kaneko et al. with Zamore and Pederson, Jr. et al. fails to render claim 1 obvious. Regardless as to how these three references may be combined, at most, the combination suggests crosslinking the central or body portion of a balloon, while optionally leaving the ends uncrosslinked for welding purposes, but fails to disclose or suggest crosslinking the cones and/or waist portions of the balloon, but not the central or body portion as recited in independent claim 1.

Claims 5 and 13 depend from claim 1 and are not obvious over this combination for at least the reasons that claim 1 is not obvious over this combination.

Reversal of the rejection of claims 5 and 13 under 35 U.S.C. §103(a) is respectfully requested.

Claim 10

Claim 10 has been rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al. in view of Zamore and in view of Pederson, Jr. et al. as applied to claim 6 above, and further in view of Smith et al. (U.S. Patent No. 6,083,587).

Claim 10 depends from claim 1.

Claim 1 is not obvious over Kaneko et al. in view of Zamore and Pederson, Jr. et

al. for the reasons discussed above. The combination fails to disclose or suggest a balloon having an uncrosslinked body portion while crosslinking the cones and/or waist portions of the balloon as recited in claim 1.

In the Final Office Action, Smith et al. is combined for a tie layer comprising a polyethylene modified with maleic anhydride. See Final Office Action, p. 10, no. 10.

However, combining a tie layer as disclosed by Smith et al. with Kaneko et al., Zamore and Pederson, Jr. et al. still fails to render claim 1 obvious for the reasons provided above. At most, the combination leads to crosslinking the body portion of a balloon, and optionally the ends, but does not lead one of skill in the art to crosslink only waist and/or cone portions of the balloon.

Claim 10 is not obvious for at least the same reasons that claim 1 is not obvious over the combination.

Reversal of the rejection of claim 10 is respectfully requested.

Claims 14-16

Claims 14-16 have been rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al in view of Zamore and in view of Pederson, Jr. et al as applied to claim 13 above, and further in view of Samuelson et al (U.S. Patent No. 6,464,683).

Claims 14-16 depend from claim 1.

Claim 1 is not obvious over Kaneko et al., Zamore and Pederson, Jr. et al. as discussed above. The combination fails to disclose or suggest a balloon wherein the waist and/or cone portions are crosslinked but not the central or body portion.

In the Final Office Action, Samuelson et al. is combined for multi-layered polymer

structures for medical devices where a tie layer (14) is formed between a first layer (12) and a second layer (16), the tie layer having a crosslinking inhibitor and as having a lower melting temperature than the first polymeric composition of the first layer.

However, combining a tie layer as disclosed by Samuelson et al. still fails to render claim 1 obvious for the reason provided above. Claims 14-16 are not obvious over this combination for at least the same reason that claim 1 is not obvious over this combination.

Reversal of the rejection of claims 14-16 under 35 U.S.C. §103(a) is respectfully requested.

Claim 17

Claim 17 has been rejected under 35 U.S.C. §103(a) as being obvious over Kaneko et al. in view of Zamore.

Claim 17 has been amended as discussed above and is now directed to an embodiment of a dilatation balloon for use in combination with a catheter device, the balloon having waist portions, cone portions and a body portion, the balloon formed of a first polymeric composition forming a first layer and having a second layer formed on at least a portion of the first layer.

The second layer comprises a second polymeric composition which is crosslinked to form a compression region on at least a portion of the balloon, the second polymer composition is crosslinked on the waist portions, the cone portions, or both, and the body portion is uncrosslinked.

As admitted in the Final Office Action, Kaneko et al. is silent as to employing crosslinking of any polymer layer whatsoever.

Zamore discloses crosslinking the entire tubular member, or crosslinking of the middle portion, and optionally leaving the ends uncrosslinked for welding the tubular member to a shaft, for example. See paragraph [0037].

As discussed previously, at most, the combination of Kaneko et al. with Zamore, leads one of ordinary skill in the art to crosslink a portion of the balloon that is the central portion or body region of the balloon, but does not lead one of skill in the art to crosslink only the waist and/or cone portions, but not the central or body portion.

As also previously discussed, Zamore teach away from crosslinking the waist portions of the balloon when welding is employed to secure the balloon to a catheter shaft. Teaching away can be employed to rebut a *prima facie* showing of obviousness. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2D at 1390.

Withdrawal of the rejection of claim 17 under 35 U.S.C. §103(a) as being obvious over Kaneko et al. in view of Zamore is respectfully requested.

CONCLUSION

Claims 1 and 5-17 are pending in the application. Applicant has addressed each of the issues presented in the Office Action. Based on the foregoing, Applicant respectfully requests reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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